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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/674,593 | 06/07/2001 | Benoit Van Den Eynde | L0461/7099 | 9143 |

7590 10/11/2002

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| EXAMINER |
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YU, MISOOK

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 10/11/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,593

Applicant(s)

EYNDE ET AL.

Examiner

Misook Yu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 8, 9, 12, 13, 15, 17-19, 21, 22, 25, 29, 30, 35, 36, 38, 41, 44, 47, 48, 50, 54, 56-62, 65-79 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Seq alignment.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,8,9,12,13,15,17-19,21,22,25,29,30,35,36,38,41,44,47,48,50,54,56-62 and 65-79.

DETAILED ACTION

Election/Restrictions

The Election/Restriction Requirement, Paper No. 11 mailed on 06/18/2002 is vacated and replaced by the following Election/Restriction Requirement.

Claims 1, 2, 8, 9, 12, 13, 15, 17-19, 21, 22, 25, 29, 30, 35, 36, 38, 41, 44, 47, 48, 50, 54, 56-62, 65-79 are pending and are subjected to restriction and/or election requirement.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The main reason for this office action is that claim 1 are drawn to two unrelated products, i.e. SEQ ID NO:1 and SEQ ID NO:4 encoding unrelated product. Although the claim asserts that the two DNA sequences are related as sense and antisense sequences, they are not related as sense and antisense sequences. Note Example 1 at page 41-46, especially page the paragraph bridging page 42 and 43 and the last paragraph at page 43, which discloses SEQ ID NO:4 and SEQ ID NO:1 are not related by the conventional definitions of antisense and sense. See the definition of antisense from On-line Medical Dictionary Retrived from the Internet, <<http://medical-dictionary.com> on 9/5/2002. Also note the sequence alignment which compares antisense of SEQ ID NO:4 to SEQ DO NO:1, which show that the instant SEQ ID NO:1 and 4 are not related as sense and antisense. Also see sequence comparison of SEQ ID NO:2 and 5, which shows they are two different proteins without structural relations to one another. Sequence comparison of SEQ ID NO:2 and 5 indicate that SEQ ID NO:1 and SEQ ID NO:4 are totally different products encoding two different human proteins. It is well known in the art that gene duplication in human genome is prevalent. See Ben-Arle et al (1994, Human Molecular Genetics, vol.3, pages 229-235).

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Group I, claim(s) 1, 2, 8, 9, 12, 13, 15, 17-19, 29, 47, 48, 54, 58, 59, 68-70, 71, 72, 73, 79, drawn to the first mentioned product in claim 1, i.e. "a nucleic acid molecule which codes for a RUR-1 sense encoded" (the specification at page 11 says that SEQ ID NO:4 is RUR-1 sense cDNA), variants, vector, host cells, SEQ ID NO:5 protein encoded by the first product, i.e. SEQ ID NO:4 cDNA, the first method of using the first product (i.e. DNA of SEQ ID NO:4) for detection of expression, vaccine.

It is noted that claims 1, 2, 8, 9, 12, 13, 15, 17-19, 29, 47, 48, 54, 58, 59, 68-70, 71, 72, 73, 79 link multiple different inventions.

Group II, claim(s) 1, 2, 8, 9, 12, 13, 25, 66, 67, 71, 72, 73, 74, 75, 76, 77, 78, drawn to a second product in the claim 1, i.e. SEQ ID NO:1 DNA, variants, or fragments, vector, host cells, kit containing nucleic acids of SEQ ID NO:1, , vaccine comprising DNA of SEQ ID NO:1, or cells expressing SEQ ID NO:2 protein, and protein of SEQ ID NO:2 or SEQ ID NO:2 fragment (i.e. SEQ ID NO:3, see page 42, the last line of the specification).

Group III, claim(s) 15, 17-19, 47, 48, 50, 54, 56-59, drawn to SEQ ID NO:2 protein encoded by SEQ ID NO:1, smaller fragments of SEQ ID NO:2,.

Group IV, claim(s) 21, 22 drawn to antibody that binds group I protein above.

Group V, claim(s) 21, 22 drawn to antibody that binds group III protein above.

Group VI, claim(s) 29, and 30 drawn to method of expression detection of, thereby diagnosing a disorder using the group II product above.

Group VII, claim(s) 29, and 30, drawn to method of expression detection of, thereby diagnosing a disorder using the group IV product above.

Group VIII, claim(s) 29, and 30, drawn to method of expression detection of, thereby diagnosing a disorder using the group V product above.

Group IX, claim(s) 29, and 30, drawn to method of expression detection of, thereby diagnosing a disorder using a new product specified as a cytolytic T lymphocyte.

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Group X, claim(s) 35, 41, drawn to 2nd method of using the group I product, i.e., treatment method using protein of SEQ ID NO:5.

Group XI, claim(s) 35, 36, and, 41, drawn to method of treatment using the group III product above.

Group XII, claim(s) 38, drawn to method of treating a disorder using CTL specific for SEQ ID NO:2 protein or its fragments.

Group XIII, claim(s) 38, drawn to method of treating a disorder using CTL specific for SEQ ID NO:5 antigen or its fragments.

Group XIV, claim(s) 44, drawn to method of enriching CTL specific for group I protein above.

Group XV, claim(s) 44, drawn to method of enriching CTL specific for group III protein above.

Group XVI Claim 47, 48, 50, 54, 79, drawn to vaccine comprising three active ingredients of SEQ ID NO: 1, SEQ ID NO: 2 protein or 3 peptide (fragment of SEQ ID NO:2 according to page 41 the last line of the specification) and cell expressing the protein.

Group XVII, claim(s) 60-62, and 65, drawn to third method using group I product, i.e. method of determining prognosis of a disorder.

Group XVIII, claim(s) 60-62, and 65 drawn to method of using group II product for determining prognosis.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-XVIII are multiple products and multiple methods using the multiple products. A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a

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process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu, Ph.D.
October 3, 2002

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
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